

Miracle-Ear®
Hearing Systems by Bausch & Lomb

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Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, S W Room 615F
Washington, D.C. 20201

Dear Secretary Shalala:

I am an owner of a Miracle-Ear franchise in north Alabama serving an eight county area providing hearing health care services to the area's hearing impaired. I am very concerned that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid regulations that would dramatically increase the cost of hearing health care and reduce access to hearing health care providers for many people in my eight county area. I have three full time centers and two service centers that are routinely manned in order to better service the patients. We also do in home service when the patient finds it too difficult to come into one of our centers. I understand that some of the rule changes may negatively impact my ability to continue in business and therefore leave many patients without the ability to reach a service center without added cost and the present convenience.

I am currently the Vice President of the Alabama Hearing Aid Association and our organization has been working with the FDA since 1993 to streamline the current FDA hearing aid regulations. Now, just weeks before the election of a new Administration, the FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like me from the marketplace. FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50-state effort by audiologists to install themselves as the sole gatekeepers to hearing health care without any medical or health policy justification.

As you may have seen, the AARP recently published a *Consumer Guide to Hearing Aids* that found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20 percent of those who need a hearing aid have one." Please don't let the FDA erect unwarranted barriers to this safe and effective medical device.

Please don't let the FDA publish its proposed hearing aid rule!

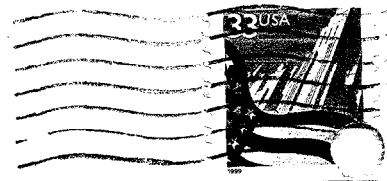
Sincerely,

John E. Vaughan BC-HIS
Board Certified Hearing Instrument Specialist
Miracle-Ear Center
Oak Hill Plaza
645 Hwy 195, Suite 114
Jasper, AL 35501
(205) 221-1108

Miracle-Ear Center
Southland Plaza
2019 6th Avenue S.E.
Decatur, AL 35601
(205) 355-3533

C5026
Miracle-Ear Center
223 B Second Avenue, SW
Cullman, AL 35055
(205) 734-0241

lar Center
d Plaza , Suite 6
Avenue S.E
AL. 35601



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